REMARKS

Status of the Claims

Claims 12-16 and 18-26 are pending in the present application. Claim 12 is amended to incorporate the features of claim 17, now canceled. Claim 27 is also canceled. Claims 20-22 and 24 are withdrawn as directed to a non-elected invention.

In view of the foregoing, no new matter is entered by way of this amendment. Reconsideration of this application is respectfully requested.

Issue Under 35 U.S.C. § 112, First Paragraph, (Written Description)

Claims 12-19, 23, 25, and 26 are rejected under 35 U.S.C. § 112, first paragraph as allegedly describing new matter, *see* Office Action, pages 2-3. The Examiner states that the claims specify "fat cells isolated from mammalian fat tissues", which is narrower than the original disclosure of "cells isolated from mammalian fat tissues." According to the Examiner, the originally filed application does not teach this feature. The Examiner states that the specification teaches that cells derived from fat tissues include fat cells, fat precursor cells and somatic cells. Accordingly, the Examiner asserts that "fat cells", *per se*, constitute new matter. Applicants respectfully traverse.

Applicants submit that the present application describes the isolation and culture of fat cells from fat tissues, *see* Example 1, page 12, lines 4-19, *especially*, page 12, line 11, which specifies "culturing mouse fat cells." Accordingly, contrary to the Examiner's assertion, the originally filed application provides adequate support for the use of only "fat cells" in the claimed methods.

In view of the foregoing, Applicants respectfully submit that the claims comply with the written description requirement. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Issues under 35 U.S.C. §103

Claims 12-16, 18, 19, 23, 25 and 26

Claims 12-16, 18, 19, 23, 25, and 26 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. 4,963,489 to Naughton *et al.*, ("Naughton"). According to the Examiner,

Naughton describes a method of co-culturing bone marrow cells and stromal cells including adipocytes with serum. The Examiner admits that Naughton does not teach or suggest the intended purpose of the claimed method, *i.e.*, differentiating bone marrow cells into myocardial precursor cells or myocardial cells. However, the Examiner states that this element is in the preamble and is not afforded patentable weight. Applicants respectfully traverse.

A preamble is entitled to patentable weight when it is "necessary to give life, meaning, and vitality" to the claim, *see* Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999). The Federal Circuit has held that a preamble may give "life, meaning and vitality" to a claim either: (1) explicitly (the claim expressly uses the preamble and the body of the claim to define the claimed invention); or (2) implicitly (proper construction of the claim requires reference to the preamble). Accordingly, when an Applicant uses the body of a claim and the preamble to define the claimed subject matter, the preamble should be accorded patentable weight.

As amended, independent claim 12 is directed to a method for differentiating mammalian bone marrow cells or cord blood-derived cells into myocardial precursor cells and/or myocardial cells without genetic engineering comprising: culturing said bone marrow cells or cord blood-derived cells with fat cells isolated from mammalian fat tissues or a culture supernatant thereof, wherein said bone marrow cells or cord blood-derived cells are induced to differentiate into myocardial precursor cells and/or myocardial cells, and wherein the cord blood-derived cells are mononuclear cells.

Initially, Applicants submit that the feature of instant claim 12, which describes that bone marrow cells or cord blood-derived cells differentiate into myocardial precursor cells and/or myocardial cells should be accorded patentable weight since it defines the claimed subject matter and is described in both the preamble and body of the claim.

Further, Applicants submit that Naughton fails to teach or suggest the differentiation of the described cells into myocardial precursor cells and/or myocardial cells, as well as additional features specified in independent claim 12. Naughton teaches that a variety of cells can be cultured in a stromal support matrix to induce proliferation. The Examiner asserts that the stromal cells in the stromal support matrix include adipocytes (fat cells). However, Naughton clearly describes that stromal cells comprise fibroblasts with or without additional cells and/or

elements, *see* column 3, lines 45-49; column 5, lines 50-52; column 7, lines 35-40; and column 15, lines 40-46 of Naughton. Naughton further teaches that fibroblasts will support the growth of cells and tissues in a three-dimensional culture system, *see* column 5, lines 59-61 of Naughton. Naughton also teaches that the three-dimensional system supports the maturation, differentiation, and segregation of cells in culture *in vitro* to form components of adult tissues analogous to counterparts found *in vivo*, *see* column 6, lines 29-33 and lines 49-51. For example, the method of Naughton is used to maximize the proliferation of multipotential hematopoietic stem cells to repopulate bone marrow or to differentiate the cells into erythroid or myeloid cells, *etc.*, *see* column 15, lines 49-55; and column 16, lines 3-7 of Naughton.

In contrast, the instantly claimed methods describe that fat cells isolated from mammalian fat tissues or a culture supernatant thereof are used to differentiate bone marrow cells or cord blood-derived cells into myocardial precursor cells or myocardial cells. The present method does not use fibroblasts and is not used to differentiate bone marrow cells into their adult tissues.

Moreover, claim 12, as amended, specifies that the cord blood-derived cells are mononuclear cells. This feature was described in previously pending claim 17, which was not rejected under 35 U.S.C. § 103(a) as obvious in view of Naughton.

In view of the foregoing, the claims are not obvious over Naughton. Accordingly, withdrawal of the rejection is respectfully requested.

Claim 27

Claim 27 is rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. 2002/0142457 to Umezawa *et al.* ("Umezawa") in view of Rangappa *et al.*, *Ann. Thorac. Surg.*, 2003, 75:775-779 ("Rangappa"), and Egger *et al.*, *Nature*, 2004, all of record.

Claim 27 is canceled. Accordingly, this rejection is moot.

CONCLUSION

In view of the above amendment and remarks, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Linda T. Parker, PhD, Registration No. 46,046, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

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Respectfully submitted,

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